UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/987,190	11/13/2001	Kazutoh Takesako	1422-0502P	6479

2292 7590 02/12/2004

BIRCH STEWART KOLASCH & BIRCH
PO BOX 747
FALLS CHURCH, VA 22040-0747

EXAMINER	
BASKAR, PADMAVATHI	

ART UNIT	PAPER NUMBER
1645	

DATE MAILED: 02/12/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/987,190	TAKESAKO ET AL.	
	Examiner	Art Unit	
	Padmavathi v Baskar	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *31 October 2003*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-20* is/are pending in the application.

4a) Of the above claim(s) *1-3,5 and 7-20* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4 and 6* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a) ☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4) ☐ Interview Summary (PTO-413) Paper No(s). _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Response to Amendment

1. Applicants response filed on 10/31/03 is acknowledged. Claims 1-20 are pending in the application. Claims 4 and 6 have been amended.

2. Claims 1-3, 5 and 7-20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention. Applicant is advised to restrict the claim 6 to SEQ.ID.NO: 2 since SEQ.ID.NO: 2 has been elected and under prosecution. Therefore, claims 4 and 6 with respect to SEQ.ID.NO: 2 are under investigation. Claim 6 (e) and (f) are withdrawn from consideration as being non-elected subject matter of the invention (SEQ.ID.NO: 6).

3. The examiner acknowledges the amendment made to the specification.

4. The text of Title 35 of the U.S. Code not reiterated herein can be found in the previous office action.

Claim objections, Informalities and Rejections Withdrawn

5. In view of amendment to the claims 4 and 6, claim objections and informalities are withdrawn.

6. In view of amendment to the claims 4 and 6 the rejection 35 U.S.C. 112, second paragraph is withdrawn.

7. In view of amendment to the claims 4 and 6 the rejection under 35 U.S.C. 101 is withdrawn.

Rejections Maintained

8. The rejection of claim 4 under 35 U.S.C. 102(b) as being anticipated by Ishiguro et al 1992 (Infection and Immunity, Vol, 60:1550-1557) is maintained as set forth in the previous office action.

Ishiguro et al discloses crude whole cell extract from Candida albicans cells (see page 1551, right column, last paragraph). Antigens were isolated by gel- electrophoresis from crude

extract (see figure 1) Antigen 25kD was strongly stained and reacted with IgE antibody indicating that this 25kD antigen had allergen activity (see figure 1 and Table 1). Therefore, the disclosed crude extract by Ishiguro et al inherently comprise a nucleic acid encoding an antigenic protein having allergen activity from Candida albicans, said protein had a molecular weight of 25kD by SDS-PAGE. Characteristics such as the partial amino acid sequence as shown in SEQ.ID.NO: 2 is considered inherent property of 25kD antigen. Thus the prior art anticipated the claimed invention.

9. The rejection of claim 6 under 35 U.S.C. 102(b) as being anticipated by Shen et al 1989 (Clinical and Experimental Allergy, Vol, 19: 191-196) is maintained as set forth in the previous office action.

Shen et al disclose isolated C.albicans from clinical specimens. Cultured cells were washed and resuspended in buffer and sonicated (see page 192 under antigenic preparation). The sonicated preparation disclosed by Shen et al inherently comprise a nucleic acid encoding a peptide having an allergen activity because the sonicated preparation contained allergenic antigens that are encoded by a nucleic acid (i.e., reactive to IgE, seepage 193, right column through page 194, figure 2 and Table 1) would hybridize with the claimed nucleic acid. Thus the prior art anticipated the claimed invention.

Applicant's arguments filed on 10/31/03 have been fully considered but they are not deemed to be persuasive.

Applicant's states that the cited references of Shen and Ishiguro fail to suggest or disclose an isolated nucleic acid as defined in the present claims and cites several case laws. Further, the applicant states that the inherency asserted by the Examiner is not a certainty based upon the prior art and it is merely speculation, although antigen components of 25kD are disclosed in Table 1 of Ishiguro, its common reaction is extremely low in comparison with antigens 175, 125, 46, 43 and 37kD disclosed as the most common IgE-binding antigen components.

Further, as shown in Table 1 of Shen, the component of the 25kD as allergenic components is not shown. Further, protein bands of 44, 41, 40, 36 and 33kD are strongly stained. Thus, when each of these references is reviewed is impossible to conclude

with any certainty that an isolated nucleic acid encoding a fungal antigen comprising an antigenic 25kD protein having a vaccine activity as disclosed in the present application is present. The Examiner simply has not provided sufficient facts. Thus, when each of these references is reviewed it is impossible to conclude with any certainty that an isolated nucleic acid encoding fungal antigen comprising an antigenic 25kD protein having vaccine activity as disclosed in the present application. The Examiner simply has not provided sufficient facts or technical reasoning, which reasonably supported determination that the allegedly inherent characteristics of the present claims necessarily flow from the teachings of the prior art. These rejections are therefore improper and should be withdrawn.

Further, Applicants point out that the fungal antigen per se encoded by the nucleic acid of claim 4, is already allowed in claim 3 of parent application, U.S. Patent 6,333,164 B1. Accordingly, the nucleic acid encoding fungal antigen should also be allowable.

The examiner disagrees with the applicant for the following reasons:

With respect to Ishiguro reference (claim 4 is rejected), applicant agrees that the 25kD antigen was disclosed in the prior art. It is the position of the examiner that the limitation that applicant is arguing such as "common reaction is extremely low in comparison with antigens 175, 125, 46, 43 and 37kD"etc is not relevant because such limitations are not set forth in the claims. The examiner has rightly pointed to the correct fungal antigen, C.albicans having 25kD antigen that has allergen activity, which was disclosed by the prior art. The examiner has established the rejection based on the scientific data including the source (C.albicans), property (molecular weight, 25kD) and function (allergen activity) of the product claimed.

With regard to Shen reference (claim 6 is rejected), the examiner rejected the claim over the sonicated preparation obtained from C.albicans that contains the component 28kD allergen which would read on the claimed 25kD because of the discrepancies often encountered in the

art between protein molecular weights when determined by different methods such as sodium dodecyl sulphate polyacrylamide gel electrophoresis, gel filtration etc. Further, protein bands of 44, 41, 40, 36 and 33kD are strongly stained etc is not relevant, as the claim does not set forth such limitations.

Finally, the characteristics of nucleic acid molecule of claim 4 or 6 are not disclosed in the present application. However, examination issues for nucleic acid are different and would not encompass protein of the issued U.S. Patent 6,333,164 B1. Therefore, issues for nucleic acid encoding fungal antigen are viewed differently and claim 4 or 6 failed to identify the nucleic acid sequence or other characteristics of the claimed nucleic acid. Therefore, these rejections are maintained.

New claim Rejections based on the amendment

Claim Rejections - 35 USC § 112

10. The following is a quotation of the second paragraph of 35 U.S.C. 112

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

11. Claims 4 and 6 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is rejected as being vague in reciting "selected from the group consisting of " as claim 4 does not recite group of fungal antigens.

Claim 6 is rejected as being vague because applicant is claiming an isolated nucleic acid molecule, which hybridizes to a nucleic acid. However, recitation of " a fungal antigen comprising an antigenic protein having a vaccine activity or an allergen activity originating from Candida albicans, wherein said antigenic protein comprises the partial amino acid sequence as

shown by SEQ ID NO: 2 in Sequence Listing and has a molecular weiqht of about 25,000 Daltons as determined by SDS-PAGE under reduced conditions" is ambiguous since there is no connection between nucleic acid and fungal antigen as written. Further Applicants have not set forth hybridization conditions in the claim or specification.

Claim Rejections - 35 USC 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless --
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

13. Claim 6 is rejected under 35 U.S.C. 102 (e) as being anticipated by Takesako et al, U.S. Patent No. 6432407.

Claim 6 is drawn to an isolated nucleic acid encoding a ' fungal antigen having a vaccine activity or an allergen activity, wherein said nucleic acid hybridizes to a nucleic acid a fungal

antigen comprising an antigenic protein having a vaccine activity or an allergen activity originating from Candida albicans, wherein said antigenic protein comprises the partial amino acid sequence as shown by SEQ ID NO: 2 in Sequence Listing and has a molecular weiqht of about 25,000 Daltons as determined by SDS-PAGE under reduced conditions.

Examiner is viewing the claim as drawn to any isolated nucleic acid molecule that hybridizes to a nucleic acid molecule of SEQ.ID.NO: 2. (Please note that the claim is rejected as being vague).

Takesako et al discloses a nucleic acid sequence SEQ.ID.NO: 7 encodes a fungal antigen and has allergen activity and hybridizes to a nucleic acid sequence (Column 19, lines, 48-67) of SEQ.ID.NO: 2 (see the sequence alignment of nucleic acid of the disclosed sequence with the SEQ.ID.NO: 2). Nucleotides AAGTAC (position 74-79) and ATCTCGGGC (position125-133) would hybridize to the claimed nucleic acid encoding fungal antigen. In the absence of evidence to the contrary, the disclosed nucleic acid would read on the claimed invention.

14. Claim 6 is rejected under 35 U.S.C. 102(b) as being anticipated by Boehringer Mannheim Biochemicals (1991 Catalog page 557), Stratagene (1991 Product Catalog, page 66), Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/1994 Catalog, pages 90-91) or New England BioLabs (Catalog 1986/1987, pages 60-62).

Claim is described and viewed as supra

Boehringer Mannheim Biochemicals (1991 Catalog page 557), Stratagene (1991 Product Catalog, page 66), discloses kits containing isolated packaged random 6-mer primers and random 9-mer primers. The random primer kits contain all possible 6 mer and 9 mer nucleic acid molecule which hybridizes with an isolated nucleic acid molecule of the claimed invention.

Gibco BRL (Catalogue & Reference Guide 1992, page 292), Promega (1993/1994 Catalog, pages 90-91) or New England BioLabs (Catalog 1986/1987, pages 60-62) each teach

a wide variety of probes, primers over 10 nucleotides which hybridizes with an isolated nucleic acid molecule of the claimed invention. Therefore, the prior art nucleic acid molecule anticipated the claimed invention.

Status of claims

15. No claims are allowed.

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP ' 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for response to this final action is set to expire THREE MONTHS from the date of this action. In the event a first response is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event will the statutory period for response expire later than SIX MONTHS from the date of this final action.

17. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Padma Baskar whose telephone number is (571) 272-0853. The examiner can normally be reached on Monday through Friday from 6:30 A.M. to 4:00 P.M. EST

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on (571) 272-0864.

LYNETTE R. F. SMITH
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600